REMARKS

The Office Action dated December 31, 2002 has been noted, and its contents carefully studied. Reconsideration of the rejection under 35 U.S.C. §§ 102, 103 and 112 is courteously requested.

With respect to the rejection under 35 U.S.C. § 112, it is noted that claims 1, 72, 78, 79, and 92 have been amended in a manner which is believed addresses the rejection, and enables the Examiner to withdraw the rejection under 35 U.S.C. § 112.

More specifically, with respect to claims 1 and 2, it is now noted that the "other data" relates to the condition of the subject. The Examiner has indicated that the term "other data" has been interpreted to mean any information that is related to the patient, and the amendment to the claims is consistent with that interpretation and properly supported by the specification, for example, such as is discussed on pages 33 and 65 with "other data" including such things as heart rate, etc. Accordingly, it is believed sufficient reasons have now been given to enable the Examiner to be able to withdraw the 35 U.S.C. § 112 rejection of these claims.

With respect to claim 79 addressing the issue of "the at least one seal," it is noted that claim 76 has been amended to depend from claim 75 which recites the at least one seal. Claim 79 depends from claim 76 and thus a proper basis has been provided for the claimed feature.

As to claim 81, reciting the "at least one serpentine capillary channel," claim 74 has been amended to depend from claim 73 which recites the "at least one serpentine capillary channel," and since claim 81 depends from claim 80 which in turn depends from claim 74, proper antecedent basis has now been provided.

With respect to claims 87 and 92, the same amendment as to claim 1 relating to "other data" has been made, and accordingly, the rejection has been addressed. Claim 92 further clarifies the limitation "modified" to encompass "in a manner to enhance sampling function," and this clarification is properly supported in the specification.

Turning now to the rejection under 35 U.S.C. §§ 102 and 103, it is respectfully urged that in light of the following discussion the claims as now amended are clearly not anticipated by or obvious in light of the cited references.

More specifically, with respect to claims 1, 72, 87, and 92, these claims relate to a transdermal sampling system, which in specific aspects relates not only input data concerning an analyte obtained transdermally, but also relates the input data to other data obtained from the subject to display information indicative of health and clinical state of the subject. In other specific aspects, the information is transmitted to another system and the sampler and detector operation are controlled. These are features that are clearly not taught or suggested by the cited references, and it is only through a hindsight interpretation of these references that the Examiner has been able to arrive at the rejections.

With respect to claim 26, the invention is recited as a microfabricated device for allowing remote monitoring of a subject. The microfabricated device also includes a transmitter/receiver for transmitting data related to an analyte detected, and for allowing control of the microfabricated device by a logic module therein. None of the references teach a microfabricated device including these specific aspects which provide the functionality discussed, and as such this claim is not anticipated by or obvious from the cited references.

As to claim 59, while not providing the transmitter/receiver feature, it recites a microfabricated device which specifically includes a detection chamber for receiving analytes, and a photonics detection system. White photonics detection systems are known from the prior art, they are not known in the context of a microfabricated device, and due to the complexity thereof, it is not obvious how such a photonics detection system would be implemented in a microfabricated device. The same comments apply to claim 63, with the difference being that claim 63 requires a patch which changes color when contacted by predetermined analytes, but again, it is not anticipated by or obvious from the cited references how such a patch system would be implemented in a microfabricated device as is disclosed in Applicants' specification.

With respect to claim 105, it recites a method of biomedically monitoring a subject's condition. The claim specifically requires ablating a subject's skin to allow interstitial fluid to perfuse therethrough and be collected. None of the references teach ablation of the skin and instead, in all cases, require perforation through needle and then add such other techniques such as ultrasound application to enhance the flow of the fluid

through the perforations. By ablating a way on the surface, the requirement for perforations is eliminated, thereby minimizing damage to the subject's skin.

Having thus generally described certain aspects of the invention, it will be clearly evident from the following detailed discussion of the cited references, that the claimed invention is not anticipated by or obvious from these references.

U.S. Patent No. 6,233,471 to Berner, et al

U.S. Patent No. 6,233,471 to Berner, et al (hereinafter Berner) discloses a method for continually or continuously measuring the concentration of an analyte present in a biological system. A raw signal is derived from the analyte detected, with the raw signal being related to the analyte concentration. Signal processing steps are then carried out in order to convert the raw signal into an initial signal output that is indicative of the analyte amount, and then further converted into a value indicative of the concentration. Berner contemplates that skin permeability is enhanced by pricking the skin with microneedles. Temperature can be detected to allow for changing conditions which might affect the measurement of the analyte accuracy.

However, as related to claims 1, 72, 87, and 92, there is nothing therein which contemplates "other data" obtained from the subject which relates to the condition of the subject, and displaying output information which is indicative of health and clinical state of the subject as determined from the relating of the input data to the other data. Moreover, there is no teaching in Berner or any of the other references of transmitting the output information to another system and controlling the operation of the at least one sampler and at least one detector. As such it is respectfully urged that the noted independent claims, and the claims dependent therefrom, are not anticipated or obvious from Berner, standing alone, or in combination with the other references.

With respect to the claims relating to a microfabricated device such as claim 26, a review of column 15 of Berner clearly reveals there is no teaching or suggestion in Berner of assembling a microfabricated device with all of the functionality of the device claimed, including, in particular with respect to claim 26, the transmitter/receiver for transmitting data relating to the analyte detected.

As to claim 105, it has already been pointed out that Berner contemplates pricking the skin, and thus there is no teaching or suggestion therein of the invention of method claim 105 for biomedically monitoring a subject's condition involving ablating the subject's skin to allow interstitial fluids to perfuse therethrough.

U.S. Patent No. 5,176,881 to Sepaniak, et al

U.S. Patent No. 5,176,881 to Sepaniak, et al (hereinafter Sepaniak) merely discloses a complex sensor for detecting fluorescence emanating from a chamber into which a sample and reagents have been introduced.

As already discussed with respect to Berner, this adds little or nothing to the teachings of Berner. More specifically, with respect to the transdermal sampling system claims, there is no teaching or suggestion in Sepaniak of detecting and providing other data relating to the condition of the subject and relating it to the information concerning the sampled analyte.

More importantly, however, even though Sepaniak teaches a fluorescence detection system, it is a fairly complicated and cumbersome system, as is evident from a review of the detailed discussion thereof. Thus, it is not apparent, even if Berner makes broad general statements about optical detection, how Sepaniak could be modified to be implemented in a system such as that of Berner.

Similarly, it is not shown or obvious from Sepaniak how the teachings of Sepaniak could be employed in the context of assembling a microfabricated device providing the functionality of Applicants' system as recited in those respective claims. Moreover, Sepaniak adds nothing to the teachings of Berner, et al, as it relates to a method of transdermal sampling though ablation.

U.S. Patent No. 6,124,597 to Shehada et al

U.S. Patent No. 6,124,597 to Shehada et al (hereinafter Shehada) discloses guiding light into a living system or a macroscopic chamber containing a sample for measurement. As stated above, claims 13, 36, 83 and 112, upon which claims 14, 37, 84 and 114 depend, are not taught or suggested by either Berner or Sepaniak. Since Shehada does not remedy the deficient teachings of Berner and Sepaniak as applied to claims 13,

36, 83 and 112, Applicants submit that these claims are allowable over the cited art. By virtue of their dependency upon these claims, claims 14, 37, 84 and 114 are patentable over the combination of Berner, Sepaniak and Shehada. Thus, it is respectfully urged that the application of the teachings of Shehada as suggested by the Examiner is an improper hindsight reconstruction of the claimed invention, and for this reason, the application of Shehada to reject claims 14, 37, 84 and 114 should be withdrawn.

U.S. Patent No. 5,458,140 to Eppstein, et al

U.S. Patent No. 5,458,140 to Eppstein, et al (hereinafter Eppstein) teaches a method of enhancing permeability of the skin or mucosa to an analyte for diagnostic purposes. Eppstein teaches controllably collecting analytes from within the body through perforations in the stratum corneum to enable monitoring of the analyte, column 4, lines 35-40. Ultrasound is used to enhance the transport of the analytes through the perforations, and thus Eppstein adds nothing to the teachings of Berner as used to support the rejection under 35 U.S.C. §§ 102 and/or 103. Moreover, as already discussed with respect to Sepaniak, it is not apparent how the teachings of Eppstein could be applied to modify those of Berner, and absent an indication or motivation therein to arrive at such modification, there would be no motivation for one of ordinary skill in the art to make a device such as has been suggested by the Examiner.

U.S. Patent No. 6,393,318 to Conn, et al

U.S. Patent No. 6,393,318 to Conn, et al (hereinafter Conn) teaches collection assembles, laminate structures, and auto sensor assemblies used in connection with a transdermal sampling device. More specifically, Conn teaches specific modifications of the Berner device. On the other hand, for the reasons given with respect to Berner, all of the claims of Applicants' invention are not anticipated or obvious, even with the teachings of Conn to those of Berner.

U.S. Patent No. 6,464,687 to Ishikawa, et al

U.S. Patent No. 6,464,687 to Ishikawa, et al (hereinafter Ishikawa) adds nothing to the references previously discussed. More specifically, Ishikawa teaches a miniature

implantable drug delivery capsule system. A small ball semiconductor capable of receiving power from outside sources is implanted within a patient's body. The ball semiconductor is associated with a drug storage medium for storing a drug and for monitoring and controlling the dispensing of the drug. The system is implanted in the body of the patient at a drug delivery site. This has nothing to do with the claimed invention as it relates to microfabricated devices, transdermal sampling systems, and while it is contemplated that drug delivery systems can be implemented in the various aspects of the invention as recited in dependent claims, there would be no motivation to implement a system such as that of Ishikawa in a system such as that of Berner, which is specifically limited to analyte detection to determine concentrations of the analyte. Thus, it is respectfully urged that the application of the teachings of Ishikawa as suggested by the Examiner is an improper hindsight reconstruction of the claimed invention, and for this reason, the application of Ishikawa to reject claims 78-79 should be withdrawn.

U.S. Patent No. 4,526,176 to Bremer et al.

U.S. Patent No. 4,526,176 to Bremer et al. (hereafter Bremer) refers to a peelable strip, e.g., tape if that is taken off of a dermal device before placing it in contact with a patient. This peelable strip is peelable and disposable. As is apparent from a reading of claims 78 and 79, the at least one seal is not peelable or disposable, but instead is a semi- and selectively permeable membrane suitable for allowing electrochemical detector to work therethrough once permeated by a heating element. Clearly a peelable disposable strip does not equate to a semi- and selectively permeable membrane that is permeable by a heating element. Thus, it is respectfully urged that the application of the teachings of Bremer as suggested by the Examiner is an improper hindsight reconstruction of the claimed invention, and for this reason, the application of Bremer to reject claims 78-79 should be withdrawn.

U.S. Patent No. 5,330,527 to Montecalvo, et al

U.S. Patent No. 5,330,527 to Montecalvo, et al (hereinafter Montecalvo) merely teaches a multipurpose medical stimulating electrode for external use in contact with the skin of a patient. The electrode is used for cardiac pacing, TENS, neuromuscular

stimulation, and other transcutaneous electrical stimulation uses. An adhesive layer may be provided around the periphery of the electrode to help bond the electrode to the skin and to seal the hydrogel matrix from the environment on all sides. Other than for the general teaching of use of an adhesive, Montecalvo adds nothing to the previously-cited references.

In fact, it is respectfully urged that the system of Montecalvo, while being in the medical field, is so far removed from the transdermal sampling system contemplated by Berner, that one of ordinary skill in the art would not look to the teachings of Montecalvo in an attempt to modify Berner to achieve certain functionality.

In fact, it is again respectfully urged that it is only after a hindsight interpretation of the references modified in a manner calculated to arrive at Applicants' claimed invention, that the rejections have been established. It is respectfully pointed out that such hindsight interpretation is impermissible under the law as it relates to 35 U.S.C. § 103 rejections. Moreover, it is also respectfully pointed out that the great number of references relied upon the Examiner in establishing the rejections clearly argues in support of Applicants' position that the claims as now amended are clearly patentable over the art of record.

For the foregoing reasons, it is respectfully urged that all the claims are clearly allowable under 35 U.S.C. §§ 102, 103 and/or 112.

Nonetheless, should the Examiner have any comments, questions or suggestions of a nature necessary to expedite prosecution of the application, he is courteously requested to telephone the undersigned at the number listed below.

Respectfully submitted,

Date: 6/30/03

By: Dawn Marie Bey

Dawn-Marie Bey
Registration No. 44,442

KILPATRICK STOCKTON LLP
Suite 900
607 14th Street, N.W.
Washington, D.C. 20005
(202) 508-5889

RALLIB01:675636.1